UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,737	11/25/2003	Bradley S. Galer	BSG 021 US	7300

35812 7590 06/09/2010

GUY DONATIELLO
ENDO PHARMACEUTICALS
100 Endo Boulevard
CHADDS FORD, PA 19317

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
06/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,737	GALER, BRADLEY S.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending and under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/22/10 was filed after the mailing date of the non-final Office Action on 12/28/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Withdrawn rejections:

Applicant's amendments and arguments filed 5/28/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hind (US 5411738) as evidenced by MedlinePlus Medical Encyclopedia: Neuralgia and Rowbotham et al. (Brain 1996, 119, 347-345) (Applicant supplied IDS filed on 11/3/09).

Hind discloses methods for treating nerve injury such as post-herpetic neuralgia with topical application of lidocaine to the skin ***at the site of the pain*** (Abstract and claims 1-8). It is inherent in the method of Hind that a patient is identified as having neuropathically induced negative sensory phenomena and the location is identified because, *as evidenced by* Rowbotham et al., the pain and negative sensory phenomena are intimately tied together. Perfoming the method of Hind inherently treats all symptoms, including numbness, of the disorder. It must. Hind uses the same compound as instantly claimed and it is well known that: "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The teachings of Rowbotham et al. clearly state that in post herpatic neuralgia, patients "***demonstrated deficits in the perception of single gentle touches, pinprick, heat and cold which were greatest in the centre of the painful area and faded toward the boundary between involved and normal skin***." (page 347, right column; Examiner added emphasis). Thus the patients had pain and loss of sensory perception simultaneously in the same location and, in the method of Hind, application of lidocaine to the skin at the site of the pain would simultaneously treat the pain and negative sensory phenomena. The Examiner is interpreting "deficits in the perception of

single gentle touches" to mean numbness because Applicant states that numbness is a sensory deficit such as a decreased ability to feel light touch (page 1, [0002, 0011] of the instant specification). In addition, *as evidenced by* MedlinePlus Medical Encyclopedia: Neuralgia, which is also known as postherpetic neuralgia, the symptoms include pain and **numbness** of the affected skin area (See symptoms pages 1-2 of 4). *Therefore, it is the Examiner's position that simply by identifying a patient with post herpatic neuralgia, where one of the symptoms is numbness, then numbness is also inherently identified and treated by application of the lidocaine to decrease the numbness in the patient. It is simply inherent in the method of Hind.* Numbness is a neuropathically-induced negative sensory phenomena (See [0011] pages 3-4 of the instant specification). Therefore, the method of Hind inherently treats any neuropathically-induced negative sensory phenomena, such as numbness, because it is a symptom and associated with the disorder and instant claims 1-4 and 9-11 are anticipated. Hind discloses applying a patch which anticipates instant claim 5 (claims 2-6). Hind discloses from about 1-20% lidocaine which anticipates instants claim 6 and 7 (claim 5). Hind discloses a lidocaine patch with a non-woven polyester backing which anticipates instant claim 8 (column 15, lines 11-16 and claim 3). Hind discloses a method in column 15, lines 11-26:

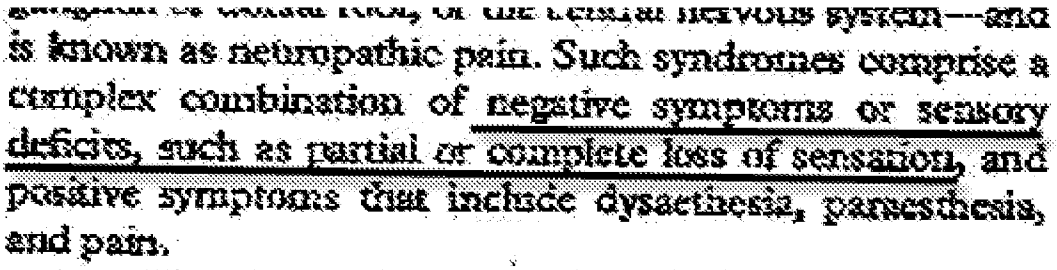
> Study Drug and Placebo
> Lidocaine patches (Lidoderm Patch) contain an adhesive of 5% lidocaine base (700 mg/patch), water, glycerin, D-sorbitol, sodium polyacrylate, sodium carboxymethylcellulose, propylene glycol and other ingredients on a non-woven polyester backing. Vehicle placebo patches are identical except for the absence of lidocaine. The size of a single patch is 10×14 cm.
> Patch Application
> Prior to patch application, the painful area to be treated was marked and then photographed based on the subject's report of (1) the borders of the area of sensory abnormality, and (2) the area of greatest pain. Up to 3 patches were applied to cover the area of greatest pain as fully as possible within the limit of 420 cm^2 Of patch area.

Since 'backing' is being interpreted to mean a cover and any numbness is inherently treated by the method and instant claims 1-11 are anticipated as discussed above.

Response to arguments:

On the one hand Applicant asserts that: "Basing a rejection on the doctrine of inherent anticipation is an acknowledgement that a primary reference does expressly disclose all the elements of an applicant's claims." This is correct. An anticipation rejection inherently meets all the limitations of the claim. On the other hand Applicant argues that Hind does not explicity disclose a method for treating the indications of neuropahtically induced sensory phenomena or numbness in patients and "somehow inherently involve treating "neuropathically-induced sensory phenomena" or "numbness" to restore sensation with the anesthetic compositions". Applicant asserts that Hind fails to satisfy the burden that an element is necessarily present because "neuropathically-induced sensory phenomena" or "numbness" are separate symptoms and may be

entirely absent in patients suffering from post-herpetic neuralgia and therefore are not necessarily present in patients suffering from post herpetic neuralgia. Respectfully, the Examiner cannot agree. Applicant's own cited art, namely Hariharasubramanian teaches that symptoms of neuropathic pain are often associated with numbness (Abstract of reference AS). Woolf et al. (reference AT) teach on page 1959:


is known as neuropathic pain. Such syndromes comprise a complex combination of negative symptoms or sensory deficits, such as partial or complete loss of sensation, and positive symptoms that include dysaesthesia, paraesthesia, and pain.

Woolf et al. clearly link sensory deficits such as complete loss of sensation, which is numbness, with neuropathic pain. While Applicant argues that "neuropathically-induced sensory phenomena" or "numbness" are not necessarily present in patients with post-herpetic neuralgia, the Examiner has shown cases where it is present. Furthermore, as Applicant recognizes, Hind teaches that: "PHN patients nearly always have a sensory deficit in the region obtained (column 1, lines 28-30). ***Thus Hind recognized and includes those patients with sensory deficits.*** The present claims do not distinguish between the patient populations. Applicant asserts an error in the Medline reference but this is merely opinion without objective evidence. Contrary to Applicant's opinion, the Rowbotham reference indicates that the pain and the numbness are co-extensive with the post-herpetic condition. This is acknowledged by Applicant in recognizing the peer reviewed work of Rowbotham. Respectfully, the Examiner does not find these arguments persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hind (US 5411738 (IDS filed on 4/30/04) in view of Wolicki (US 2004/0101582) as evidenced by MedlinePlus Medical Encyclopedia: Neuralgia and Rowbotham et al. (Brain 1996, 119, 347-345) (Applicant supplied IDS filed on 11/3/09).

Applicant claims a method for treating neuropathically-induced negative sensory phenomena comprising applying an anesthetic topically to the skin of a patient suffering from neuropathic negative sensory phenomena at or near the locus of the negative sensory phenomena.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The references of Hind, Rowbotham et al., and MedlinePlus are discussed in detail above and those discussions are hereby incorporated by reference.

Wolicki teaches in claim 6 the equivalence of various benzoic acid derivatives for the treatment of neuropathy:

> 6. The topical composition of claim 2, wherein said additional ingredient is selected from the group consisting of: capsaicin, lidocaine, bupivacaine, mepivacaine, ropivacaine, tetracaine, etidocaine, chloroprocaine, prilocaine, procaine, benzocaine, dibucaine, dyclonine hydrochloride, pramoxine hydrochloride, benzocaine, and proparacaine.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Hind is that Hind do not expressly teach various benzoic acid derivatives in the method. This deficiency in Hind is cured by the teachings of Wolicki.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add other benzoic acid derivatives, as suggested by Wolicki, to the method of Hind and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the art teaches the benzoic acid derivatives to be equivalent in methods of treating neuropathy. The expected result remains treatment of the neuropathy.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

First, Applicant asserts that the Medline is not prior art and that Medline cannot be used under 35 USC 102. Respectfully, the Examiner cannot agree. From MPEP 2131.01 III: Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124. The rejection is proper as the Examiner stated in the last response.

Second, Applicant argues that the obviousness rejection improperly relies on the doctrine of inherent anticipation. This is incorrect as the Examiner has brought in the reference of Wolicki (US 2004/0101582) for the teaching of benzoic acid derivatives that are not taught by the primary reference.

Third, Applicant argues that the claims are not obvious over the combination of references. The Examiner cannot agree for the reasons set forth *supra* and has set forth a proper prima facie case above.

Fourth, Applicant asserts that one of ordinary skill in the art would not be motivated to perform the claimed methods or have a reasonable expectation of success because nothing in the cited references suggests that a topically applied anesthetic can cause sensation to return or improve tactile response and sensory loss in patients with neuropathically induced negative sensory phenomena or numbness of the skin. First of all, the practitioner following the methods of Hind already performs the instant method and secondly such an argument is pointless and brings into question enablement issues because neither has Applicant shown any objective evidence to demonstrate it works. *It remains the Examiner's position that this is simply a method of treating a painful neuralgia in the disguise of treating a symptom of the disorder.*

No unexpected results have been shown. Synergy has not been argued. Respectfully, Applicant's arguments are not persuasive and the claims remain rejected.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

Primary Examiner, Art Unit 1616